P21289.P12

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Attorney Docket No. P21289

In re application of	: H. ENDO et al.	**Mail Stop Amendment**
Serial No.	: 09/869,334	Group Art Unit: 1652
Filed	: September 26, 2001	Examiner: D. M. Ramirez
For	: PROCESS FOR PRODUCING HMG-COA REDUCTASE INHIBITOR	

Mail Stop Amendment
COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

Transmitted herewith is an election with traverse in the above-captioned application.

___ Small Entity Status of this application under 37 C.F.R. 1.9 and 1.27 has been established by a previously filed statement.
___ A verified statement to establish small entity status under 37 C.F.R. 1.9 and 1.27 is enclosed.
___ A Request for Extension of Time.
_X_ No additional fee is required.

The fee has been calculated as shown below:

Claims After Amendment	No. Claims Previously Paid For	Present Extra	Small Entity		Other Than A Small Entity	
			Rate	Fee	Rate	Fee
Total Claims: 39	*39	0	x 9=	$	x 18=	$0.00
Indep. Claims: 8	**8	0	x 43=	$	x 86=	$0.00
Multiple Dependent Claims Presented			+145=	$	+290=	$0.00
Extension Fees for Month				$		$0.00
			Total:	$	Total:	$0.00

*If less than 20, write 20
**If less than 3, write 3
___ Please charge my Deposit Account No. 19-0089 in the amount of $_____.

_N/A_ A Check in the amount of $_____ to cover the *filing/extension* fee is included.
_X_ The U.S. Patent and Trademark Office is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 19-0089.
_X_ Any additional filing fees required under 37 C.F.R. 1.16.
_X_ Any patent application processing fees under 37 C.F.R. 1.17, including any required extension of time fees in any concurrent or future reply requiring a petition for extension of time for its timely submission (37 CFR 1.136) (a)(3)

Bruce H. Bernstein
Reg. No. 29,027

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Hirofumi ENDO et al.

Art Unit: 1652

Serial No. : 09/869,334

Examiner: D. M. Ramirez

Filed : September 26, 2001

For : PROCESS FOR PRODUCING HMG-COA REDUCTASE INHIBITOR

ELECTION WITH TRAVERSE

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

This is in response to the requirement for restriction under 35 U.S.C. 121 and 372 mailed from the U.S. Patent and Trademark Office on April 13, 2004, which sets a one month shortened statutory period for response until May 13, 2004.

Applicant notes that this response is being filed prior to the expiration of the one month shortened statutory period for response, whereby an extension of time should not be necessary to maintain the pendency of the application. However, if any extensions of time are required to maintain the pendency of this application, this is an express request for any required extension of time, and authorization to charge any required fee to Deposit Account No. 19-0089.

Reconsideration and withdrawal of the requirement for restriction and election of species are respectfully requested in view of the remarks which follow:

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Restriction Requirement

Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:

Group I, claims 1-6, drawn in part to a single protein from B. subtilis ATCC6051 which has the activity of producing compounds IIa or IIb;

Group II, claims 1-6, drawn in part to a single protein from B. megaterium ATCC10778 which has the activity of producing compounds IIa or IIb;

Group III, claims 1-6, drawn in part to a single protein from B. megaterium ATCC11562 which has the activity of producing compounds IIa or IIb;

Group IV, claims 1-6, drawn in part to a single protein from B. megaterium ATCC13402 which has the activity of producing compounds IIa or IIb;

Group V, claims 1-6, drawn in part to a single protein from B. megaterium ATCC15177 which has the activity of producing compounds IIa or IIb;

Group VI, claims 1-6, drawn in part to a single protein from B. megaterium ATCC15450 which has the activity of producing compounds IIa or IIb;

Group VII, claims 1-6, drawn in part to a single protein from B. megaterium ATCC19213 which has the activity of producing compounds IIa or IIb;

Group VIII, claims 1-6, drawn in part to a single protein from B. megaterium IAM1032 which has the activity of producing compounds IIa or IIb;

Group IX, claims 1-6, drawn in part to a single protein from B. laterosporus ATCC4517 which has the activity of producing compounds IIa or IIb;

Group X, claims 1-6, drawn in part to a single protein from B. pumilus FERM BP-2064 which has the activity of producing compounds IIa or IIb;

Group XI, claims 1-6, drawn in part to a single protein from B. badius ATCC14574 which has the activity of producing compounds IIa or IIb;

Group XII, claims 1-6, drawn in part to a single protein from B. brevis NRRL B-8029 which has the activity of producing compounds IIa or IIb;

Group XIII, claims 1-6, drawn in part to a single protein from B. alvei ATCC6344 which has the activity of producing compounds IIa or IIb;

Group XIV, claims 1-6, drawn in part to a single protein from B. circulans NTCT-2610 which has the activity of producing compounds IIa or IIb;

Group XV, claims 1-6, drawn in part to a single protein from B. macerans NCIMB-9368 which has the activity of producing compounds IIa or IIb;

Group XVI, claims 1-4, 7 drawn in part to a single protein from B. sp. FERM BP-6029 which has the activity of producing compounds IIa or IIb;

Group XVII, claims 1-4, 7 drawn in part to a single protein from B. sp. FERM BP-6030 which has the activity of producing compounds IIa or IIb;

Group XVIII, claims 1-5, drawn in part to a single protein from B. sphaericus which has the activity of producing compounds IIa or IIb;

Group XIX, claims 1-5, drawn in part to a single protein from B. stearothermophilus which has the activity of producing compounds IIa or IIb;

Group XX, claims 1-5, drawn in part to a single protein from B. cereus which has the activity of producing compounds IIa or IIb;

Group XXI, claims 1-5, 8, drawn in part to the polypeptide SEQ. ID. NO: 1;

Group XXII, claims 1-5, 9-13, drawn in part to the polypeptide SEQ. ID. NO: 42;

Group XXIII, claims 1-5, 9-13, drawn in part to the polypeptide SEQ. ID. NO: 45;

Group XXIV, claims 14, 21-39, drawn in part to the polypeptide SEQ. ID. NO: 2, vectors and host cells comprising said polynucleotide, a method for producing a compound using the host cells, and a method of recombinantly producing the corresponding polypeptide;

Group XXV, claims 15-16, 18-20, 39, drawn in part to the polynucleotide SEQ. ID. NO: 41;

Group XXVI, claims 15-16, 18-20, 39, drawn in part to the polynucleotide SEQ. ID. NO: 43;

Group XXVII, claims 15-16, 18-20, 39, drawn in part to the polynucleotide SEQ. ID. NO: 44; and

Group XXVIII, claims 17, drawn in part to a single polynucleotide encoding a Bacillus protein which has the activity of producing compounds IIa or IIb.

The Examiner asserts that the inventions listed as Groups I to XXVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features because: (1) the technical feature of Group XXI is the polypeptide of SEQ ID NO: 1, which is shown by Kunst et al. to lack novelty or inventive step; (2) although the polypeptides of Groups I to XXIII and Groups XXIV to XXVIII share a common property in that they are either nucleic acids or proteins, the compounds are not regarded as being of similar nature because all the alternatives do not share a common structure or function; and (3) Groups I to XXIII are directed to proteins with the technical feature of being polypeptides capable of producing compound X from compound Y, whereas Groups XXIV to XXVIII are directed to nucleic acids which have the special technical feature of being polynucleotides which encode proteins capable of producing compound X from compound Y, not shared by Groups I to XXIII.

Election

In response to the requirement for restriction, Applicants elect the invention of Group XXIV (claims 14, and 21-39), with traverse.

However, for the reasons set forth below, Applicant submits that the restriction requirement is improper, and should be withdrawn, whereby an action on the merits of all of the pending claims is warranted.

Traverse

Notwithstanding the election of the claims of Group XXIV in order to be responsive to the requirement for restriction, Applicant respectfully traverses the requirement.

The Examiner is reminded that in determining unity of invention, the criteria set forth in 37 C.F.R. 1.475 must be considered. Specifically, Applicants note that 37 C.F.R. 1.475 provides:

> Unity of invention before the International Searching Authority, the International Preliminary Examining Authority, and during the national stage.
>
> (a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.
>
> (b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
>
> (1) A product and a process specially adapted for the manufacture of said product; or
>
> (2) A product and process of use of said product; or
>
> (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
>
> (4) A process and an apparatus or means specifically designed for carrying out the

said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).

(e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Applicants point out that in determining unity of invention the criteria set forth in 37 C.F.R. 1.475 must be considered. Thus, in stating the restriction requirement, the requirement must state why unity of invention is lacking at least under 1.475(a) and (b). Therefore, the restriction requirement is improper for not discussing the various sections of 1.475.

Moreover, 1.475(b)(1) states that an international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn to a product and a process specially adapted for the manufacture of said product. In the instant situation, independent claim 14 is directed to an isolated DNA having the nucleotide sequence of SEQ ID No: 2, and dependent claims 15 is directed to an isolated DNA which hybridizes with the DNA of claim 14 under stringent conditions, and encodes a protein having an activity of producing compound (IIa) or compound (IIb) from compound (I-a) or compound (I-b). For unity purposes, DNA that hybridizes with another DNA having a certain nucleotide sequence comprises a nucleotide sequence that can be considered to share a special technical feature with the DNA having the certain nucleotide sequence. A DNA which hybridizes with another DNA can have a similar structure with that of the other DNA. Therefore, claims 14-16 fulfill the unity of invention in accordance with 37

Furthermore, it is apparent from the disclosure in the specification that the DNAs having a nucleotide sequence of SEQ ID No: 41, 43, or 44 are similar with each other in structure, for examination purposes, and the proteins encoded by said DNAs have the same activity as that of the protein encoded by the DNA having a nucleotide sequence of SEQ ID No: 2. Therefore, Groups XXIV, XXV, XXVI, and XXVII fulfill the unity of invention in accordance with 37 C.F.R. 1.475..

Additionally, claim 21 recites claims 15 and 16. Therefore, Groups XXV, XXVI, and XXVII should include claims 15 and 16 along with claims 18 to 39.

As discussed above, we respectfully request reconsideration of all the pending claims, especially claims 14-16 and 18-39 because they fulfill the unity of invention in accordance to 37 C.F.R. 1.475, and should be included in a single application.

Still further, there should be no undue burden to examine all of the pending claims, because, as discussed above, the International Searching Authority has already performed a search of each of the pending claims.

In view of the foregoing, it is respectfully requested that the Examiner seriously reconsider the requirement for restriction, and withdraw the same so as to give an examination on the merits on all of the claims pending in this application. In any event, the claims should be rejoined upon allowance of the elected claims.

CONCLUSION

For the reasons discussed above, it is respectfully submitted that the requirement for restriction is improper because unity of invention is present, and the requirement should be

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withdrawn.

Withdrawal of the requirement for the restriction with examination of all pending claims is respectfully requested.

Favorable consideration with early allowance of the application is most earnestly requested.

If the Examiner has any questions, or wishes to discuss this matter, the Examiner is requested to call the undersigned at the telephone number indicated below.

Respectfully submitted,
Hirofumi ENDO et al.

Bruce H. Bernstein
Reg. No. 29,027 ~~33,094~~ 33,094

May 13, 2004
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